

Food and Drug Administration, HHS

§ 14.171

listed in §14.100 or to any advisory committee established under any other procedure that is mutually agreeable. Once the Commissioner has established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(b) Members of a color additive advisory committee are subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee may by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) When a matter is referred to a color additive advisory committee, all related costs, including personal compensation of committee members, travel, materials, and other costs, are borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs includes personal compensation of committee members at a rate not to exceed \$128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee, a special advance deposit is to be made in the amount of \$2,500. Where required, further advances in increments of \$2,500 each are to be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses will be refunded to the depositor.

(c) All deposits and fees required by this section are to be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par in Washington, DC. All deposits and fees are to be forwarded to the Associate Commissioner for Management and Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville,

MD 20857, and after appropriate record of them is made, they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in the Commissioner's judgment, such action will promote the public interest. Any person who believes that payment of these fees will be a hardship may petition the Commissioner under §10.30 to waive or refund the fees.

Subpart I—Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before FDA, including whether the available information is adequate to support a determination that—

(1) A particular IND study may properly be conducted;

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing; or

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of an advisory committee on the initiative of FDA.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a